

§212.5

and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

§212.5 To what drugs do the regulations in this part apply?

(a) *Application solely to PET drugs.* The regulations in this part apply only to the production, quality assurance, holding, and distribution of PET drugs. Any human drug that does not meet the definition of a PET drug must be manufactured in accordance with the current good manufacturing practice requirements in parts 210 and 211 of this chapter.

(b) *Investigational and research PET drugs.* For investigational PET drugs for human use produced under an investigational new drug application in accordance with part 312 of this chapter, and PET drugs produced with the approval of a Radioactive Drug Research Committee in accordance with part 361 of this chapter, the requirement under the act to follow current good manufacturing practice is met by complying with the regulations in this part or by producing PET drugs in accordance with Chapter 823, “Radiopharmaceuticals for Positron Emission Tomography—Compounding,” May 1, 2009, pp. 365–369, 32d ed. of the United States Pharmacopeia (USP) National Formulary (NF) (USP 32/NF 27) (2009). The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, Geeta M. Tirumalai, 301-816-8352, e-mail: gt@usp.org, Internet address: <http://www.usp.org/USPNE/notices>. You may inspect a copy at the Food and Drug Administration Biosciences Library, 10903 New Hampshire Ave., Silver Spring, MD, 20993-0002, 301-796-3504, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

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Subpart B—Personnel and Resources

§212.10 What personnel and resources must I have?

You must have a sufficient number of personnel with the necessary education, background, training, and experience to perform their assigned functions. You must have adequate resources, including facilities and equipment, to enable your personnel to perform their functions.

Subpart C—Quality Assurance

§212.20 What activities must I perform to ensure drug quality?

(a) *Production operations.* You must oversee production operations to ensure that each PET drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

(b) *Materials.* You must examine and approve or reject components, containers, closures, in-process materials, packaging materials, labeling, and finished dosage forms to ensure compliance with procedures and specifications affecting the identity, strength, quality, or purity of a PET drug.

(c) *Specifications and processes.* You must approve or reject, before implementation, any initial specifications, methods, processes, or procedures, and any proposed changes to existing specifications, methods, processes, or procedures, to ensure that they maintain the identity, strength, quality, and purity of a PET drug. You must demonstrate that any change does not adversely affect the identity, strength, quality, or purity of any PET drug.

(d) *Production records.* You must review production records to determine whether errors have occurred. If errors have occurred, or a production batch or any component of the batch fails to meet any of its specifications, you must determine the need for an investigation, conduct investigations when necessary, and take appropriate corrective actions.

(e) *Quality assurance.* You must establish and follow written quality assurance procedures.